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October 15, 1992

Document Processing Center (TS-790)  
Office of Pollution Prevention and Toxics  
Environmental Protection Agency  
401 M Street., S.W.  
Washington, D.C. 20460  
Attn: Section 8(e) Coordinator (CAP Agreement)

Dear Coordinator:

8ECAP-0025

On behalf of the Regulatee and pursuant to Unit II B.1.b. and Unit II C of the 6/28/91CAP Agreement, E.I. Du Pont de Nemours and Co. hereby submits (*in triplicate*) the attached studies. Submission of this information is voluntary and is occasioned by unilateral changes in EPA's standard as to what EPA now considers as reportable information. Regulatee's submission of information is made solely in response to the new EPA §8(e) reporting standards and is not an admission: (1) of TSCA violation or liability; (2) that Regulatee's activities with the study compounds reasonably support a conclusion of substantial health or environmental risk or (3) that the studies themselves reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which were not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide" states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due processes issues and clouds the appropriate reporting standard by which regulated persons can assure TSCA Section 8(e) compliance.

For Regulatee,

Mark H. Christman  
Counsel  
Legal D-7158  
1007 Market Street  
Wilmington, DE 19898  
(302) 774-6443

mm

2/15/95

## ATTACHMENT 1

Submission of information is made under the 6/28/91 CAP Agreement, Unit II. This submission is made voluntarily and is occasioned by recent changes in EPA's TSCA §8(e) reporting standard; such changes made, for the first time in 1991 and 1992 without prior notice and in violation of Regulatee's constitutional due process rights. Regulatee's submission of information under this changed standard is not a waiver of its due process rights; an admission of TSCA violation or liability, or an admission that Regulatee's activities with the study compounds reasonably support a conclusion of substantial risk to health or to the environment. Regulatee has historically relied in good faith upon the 1978 Statement of Interpretation and Enforcement Policy criteria for determining whether study information is reportable under TSCA §8(e), 43 Fed Reg 11110 (March 16, 1978). EPA has not, to date, amended this Statement of Interpretation.

After CAP registration, EPA provided the Regulatee the June 1, 1991 "TSCA Section 8(e) Reporting Guide". This "Guide" has been further amended by EPA, EPA letter, April 10, 1992. EPA has not indicated that the "Reporting Guide" or the April 1992 amendment supersedes the 1978 Statement of Interpretation. The "Reporting Guide" and April 1992 amendment substantively lowers the Statement of Interpretation's TSCA §8(e) reporting standard<sup>2</sup>. This is particularly troublesome as the "Reporting Guide" states criteria, applied retroactively, which expands upon and conflicts with the Statement of Interpretation.<sup>3</sup> Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" and the April 1992 amendment clouds the appropriate standard by which regulated persons must assess information for purposes of TSCA §8(e).

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<sup>2</sup>In sharp contrast to the Agency's 1977 and 1978 actions to soliciting public comment on the proposed and final §8(e) Policy, EPA has unilaterally pronounced §8(e) substantive reporting criteria in the 1991 Section 8(e) Guide without public notice and comment. See 42 Fed Reg 45362 (9/9/77), "Notification of Substantial Risk under Section 8(e): Proposed Guidance".

<sup>3</sup>A comparison of the 1978 Statement of Interpretation and the 1992 "Reporting Guide" is appended.

Throughout the CAP, EPA has mischaracterized the 1991 guidance as reflecting "longstanding" EPA policy concerning the standards by which toxicity information should be reviewed for purposes of §8(e) compliance. Regulatee recognizes that experience with the 1978 Statement of Interpretation may cause a review of its criteri. Regulatee supports and has no objection to the Agency's amending reporting criteria *provided that* such amendment is not applied to the regulated community in an unfair way. However, with the unilateral announcement of the CAP under the auspices of an OCM enforcement proceeding, EPA has wrought a terrific unfairness since much of the criteria EPA has espoused in the June 1991 Reporting Guide and in the Agency's April 2, 1992 amendment is new criteria which does not exist in the 1978 Statement of Interpretation and Enforcement Policy.

The following examples of new criteria contained in the "Reporting Guide" that is not contained in the Statement of Interpretation follow:

- o even though EPA expressly disclaims each "status report" as being preliminary evaluations that should not be regarded as final EPA policy or intent<sup>4</sup>, the "Reporting Guide" gives the "status reports" great weight as "sound and adequate basis" from which to determine mandatory reporting obligations. ("Guide" at page 20).
- o the "Reporting Guide" contains a matrix that establishes new numerical reporting "cutoff" concentrations for acute lethality information ("Guide" at p. 31). Neither this matrix nor the cutoff values therein are contained in the Statement of Interpretation. The regulated community was not made aware of these cutoff values prior to issuance of the "Reporting Guide" in June, 1991.
- o the "Reporting Guide" states new specific definitional criteria with which the Agency, for the first time, defines as 'distinguishable neurotoxicological effects'; such criteria/guidance not expressed in the 1978 Statement of Interpretation.<sup>5</sup>;
- o the "Reporting Guide" provides new review/ reporting criteria for irritation and sensitization studies; such criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy.
- o the "Reporting Guide" publicizes certain EPA Q/A criteria issued to the Monsanto Co. in 1989 which are not in the Statement of Interpretation; have never been published in the Federal Register or distributed by the EPA to the Regulatee. Such Q/A establishes new reporting criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy.

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<sup>4</sup>The 'status reports' address the significance, if any, of particular information reported to the Agency, rather than stating EPA's interpretation of §8(e) reporting criteria. In the infrequent instances in which the status reports contain discussion of reportability, the analysis is invariably quite limited, without substantial supporting scientific or legal rationale.

<sup>5</sup> See, e.g., 10/2/91 letter from Du Pont to EPA regarding the definition of 'serious and prolonged effects' as this term may relate to transient anesthetic effects observed at lethal levels; 10/1/91 letter from the American Petroleum Institute to EPA regarding clarification of the Reporting Guide criteria.

In discharging its responsibilities, an administrative agency must give the regulated community fair and adequate warning to as what constitutes noncompliance for which penalties may be assessed.

Among the myriad applications of the due process clause is the fundamental principle that statutes and regulations which purport to govern conduct must give an adequate warning of what they command or forbid.... Even a regulation which governs purely economic or commercial activities, if its violation can engender penalties, must be so framed as to provide a constitutionally adequate warning to those whose activities are governed.

Diebold, Inc. v. Marshall, 585 F.2d 1327, 1335-36 (D.C. Cir. 1978). See also, Rollins Environmental Services (NJ) Inc. v. U.S. Environmental Protection Agency, 937 F. 2d 649 (D.C. Cir. 1991).

While neither the are rules, This principle has been applied to hold that agency 'clarification', such as the Statement of Interpretation, the "Reporting Guide" nor the April 1992 amendments will not applied retroactively.

...a federal court will not retroactively apply an unforeseeable interpretation of an administrative regulation to the detriment of a regulated party on the theory that the post hoc interpretation asserted by the Agency is generally consistent with the policies underlying the Agency's regulatory program, when the semantic meaning of the regulations, as previously drafted and construed by the appropriate agency, does not support the interpretation which that agency urges upon the court.

Standard Oil Co. v. Federal Energy Administration, 453 F. Supp. 203, 240 (N.D. Ohio 1978), aff'd sub nom. Standard Oil Co. v. Department of Energy, 596 F.2d 1029 (Em. App. 1978):

The 1978 Statement of Interpretation does not provide adequate notice of, and indeed conflicts with, the Agency's current position at §8(e) requires reporting of all 'positive' toxicological findings without regard to an assessment of their relevance to human health. In accordance with the statute, EPA's 1978 Statement of Interpretation requires the regulated community to use scientific judgment to evaluate the significance of toxicological findings and to determining whether they reasonably support a conclusion of a substantial risk. Part V of the Statement of Interpretation urges persons to consider "the fact or probability" of an effect's occurrence. Similarly, the 1978 Statement of Interpretation stresses that an animal study is reportable only when "it contains reliable evidence ascribing the effect to the chemical." 43 Fed Reg. at 11112. Moreover, EPA's Statement of Interpretation defines the substantiality of risk as a function of both the seriousness of the effect and the probability of its occurrence. 43 Fed Reg 11110 (1978). Earlier Agency interpretation also emphasized the "substantial" nature of a §8(e) determination. See 42 Fed Reg 45362, 45363

(1977). [Section 8(e) findings require "extraordinary exposure to a chemical substance...which critically imperil human health or the environment"].

The recently issued "Reporting Guide" and April 1992 Amendment guidance requires reporting beyond and inconsistent with that required by the Statement of Interpretation. Given the statute and the Statement of Interpretation's explicit focus on substantial human or environmental risk, whether a substance poses a "substantial risk" of injury requires the application of scientific judgment to the available data on a case-by-case basis.

If an overall weight-of-evidence analysis indicates that this classification is unwarranted, reporting should be unnecessary under §8(e) because the available data will not "reasonably support the conclusion" that the chemical presents a substantial risk of serious adverse consequences to human health.

Neither the legislative history of §8(e) nor the plain meaning of the statute support EPA's recent lowering of the reporting threshold that TSCA §8(e) was intended to be a sweeping information gathering mechanism. In introducing the new version of the toxic substances legislation, Representative Eckhart included for the record discussion of the specific changes from the version of H. R. 10318 reported by the Consumer Protection and Finance Subcommittee in December 1975. One of these changes was to modify the standard for reporting under §8(e). The standard in the House version was changed from "causes or contributes to an unreasonable risk" to "causes or significantly contributes to a substantial risk". This particular change was one of several made in TSCA §8 to avoid placing an undue burden on the regulated community. The final changes to focus the scope of Section 8(e) were made in the version reported by the Conference Committee.

The word "substantial" means "considerable in importance, value, degree, amount or extent". Therefore, as generally understood, a "substantial risk" is one which will affect a considerable number of people or portion of the environment, will cause serious injury and is based on reasonably sound scientific analysis or data. Support for the interpretation can be found in a similar provision in the Consumer Product Safety Act. Section 15 of the CPSA defines a "substantial product hazard" to be:

"a product defect which because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, creates a substantial risk of injury to the public."

Similarly, EPA has interpreted the word 'substantial' as a quantitative measurement. Thus, a 'substantial risk' is a risk that can be quantified, *See*, 56 Fed Reg 32292, 32297 (7/15/91). Finally, since information pertinent to the exposure of humans or the environment to chemical substances or mixtures may be obtained by EPA through Sections 8(a) and 8(d) regardless of the degree of potential risk, §8(e) has specialized function. Consequently, information subject to §8(e) reporting should be of a type which would lead a reasonable man to conclude that some type action was required immediately to prevent injury to health or the environment.

## Attachment

**Comparison:**

Reporting triggers found in the 1978 "Statement of Interpretation/ Enforcement Policy", 43 Fed Reg 11110 (3/16/78) and the June 1991 *Section 8(e) Guide*.

| <b>TEST TYPE</b><br><hr/>                      | <b>1978 POLICY<br/>CRITERIA EXIST?</b> | <b>New 1991 GUIDE<br/>CRITERIA EXIST?</b> |
|--|--|---|
| <b>ACUTE LETHALITY</b>                         |  |   |
| Oral   | N}                                     | Y}  |
| Dermal   | N}                                     | Y}  |
| Inhalation (Vapors)                            | } <sup>6</sup>                         | } <sup>7</sup>                            |
| aerosol  | N}                                     | Y}  |
| dusts/ particles                               | N}                                     | Y}  |
| <b>SKIN IRRITATION</b>                         | N                                      | Y <sup>8</sup>                            |
| <b>SKIN SENSITIZATION (ANIMALS)</b>            | N                                      | Y <sup>9</sup>                            |
| <b>EYE IRRITATION</b>                          | N                                      | Y <sup>10</sup>                           |
| <b>SUBCHRONIC<br/>(ORAL/DERMAL/INHALATION)</b> | N                                      | Y <sup>11</sup>                           |
| <b>REPRODUCTION STUDY</b>                      | N                                      | Y <sup>12</sup>                           |
| <b>DEVELOPMENTAL TOX</b>                       | Y <sup>13</sup>                        | Y <sup>14</sup>                           |

<sup>6</sup>43 Fed Reg at 11114, comment 14:

"This policy statements directs the reporting of specific effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemical. Unknown effects occurring during such a range test may have to be reported if they are those of concern to the Agency and if the information meets the criteria set forth in Parts V and VII."

<sup>7</sup>Guide at pp.22, 29-31.

<sup>8</sup>Guide at pp-34-36.

<sup>9</sup>Guide at pp-34-36.

<sup>10</sup>Guide at pp-34-36.

<sup>11</sup>Guide at pp-22; 36-37.

<sup>12</sup>Guide at pp-22

<sup>13</sup>43 Fed Reg at 11112

"Birth Defects" listed.

<sup>14</sup>Guide at pp-22

|                        |                 |                 |
|------------------------|-----------------|-----------------|
| NEUROTOXICITY          | N               | Y <sup>15</sup> |
| CARCINOGENICITY        | Y <sup>16</sup> | Y <sup>17</sup> |
| MUTAGENICITY           |                 |                 |
| <i>In Vitro</i>        | Y <sup>18</sup> | Y <sup>19</sup> |
| <i>In Vivo</i>         | Y}              | Y}              |
| ENVIRONMENTAL          |                 |                 |
| Bioaccumulation        | Y}              | N               |
| Bioconcentration       | Y <sup>20</sup> | N               |
| Oct/water Part. Coeff. | Y}              | N               |
| Acute Fish             | N               | N               |
| Acute Daphnia          | N               | N               |
| Subchronic Fish        | N               | N               |
| Subchronic Daphnia     | N               | N               |
| Chronic Fish           | N               | N               |
| AVIAN                  |                 |                 |
| Acute                  | N               | N               |
| Reproductive           | N               | N               |
| Reproductive           | N               | N               |

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<sup>15</sup>Guide at pp-23; 33-34.

<sup>16</sup>43 Fed Reg at 11112  
"Cancer" listed

<sup>17</sup>Guide at pp-21.

<sup>18</sup>43 Fed Reg at 11112; 11115 at Comment 15

"Mutagenicity" listed/ *in vivo* vs *invitro* discussed; discussion of "Ames test".

<sup>19</sup>Guide at pp-23.

<sup>20</sup>43 Fed Reg at 11112; 11115 at Comment 16.



**CAS # 107-22-2**

**Chem: "Glyoxal"**

**Title: Letter**

**Date: 10/5/65**

**Summary of Effects: LD50 range less than 100 mg/kg (I.P.)  
800-1600 mg/kg (P.O.)**

# EASTMAN KODAK COMPANY

ROCHESTER, NEW YORK 14650

PLEASE ADDRESS REPLY TO  
KODAK PARK WORKS

TELEPHONE  
AREA CODE 716 GLADSTONE 8-1000

October 5, 1965

File: C-02932

Mr. James Morgan  
Haskell Laboratories  
E. I. Dupont de Nemours and Company  
Newark, Delaware

Dear Jim:

Dr. Warren Jones of our laboratory has called my attention to your inquiry of September 28 regarding Glyoxal. As you had noticed both in the introductory text under 'Aliphatic Dialdehydes' and in the table of data we were in variance with Carbide on the matter of its irritation and general toxicity. I gave both Henry Smyth's values for the oral rat LD<sub>50</sub> and also our own values as indicated in the footnote of Table 7 on page 1981. We do have data in other species, however, which confirms the relative high degree of toxicity of the material and we also have clear cut evidence in the guinea pig of a severe degree of skin reaction. The material we were using was a 30 per cent solution in water. This solution was stabilized with small amounts of phosphoric acid. As you undoubtedly are aware, Glyoxal is an extremely unstable material and polymerizes very rapidly. This is the only possible explanation I can think of to account for the variance between our results and Henry Smyth's. Possibly his solutions had partially polymerized or else they were given in a very much more dilute form.

To supplement the data that is in Patty you may be interested in the following information:

| <u>Species</u> | <u>Route</u> | <u>LD<sub>50</sub></u> |
|----------------|--------------|------------------------|
| Mouse          | P.O.         | 400-800 mg/kg          |
| Mouse          | I.P.         | 200-400 mg/kg          |
| Rat            | P.O.         | 200-400 mg/kg          |
| Rat            | I.P.         | <100 mg/kg             |
| Guinea Pig     | P.O.         | 800-1600 mg/kg         |
| Guinea Pig     | I.P.         | 100-200 mg/kg          |

In all cases the symptoms were not very dramatic and consisted principally of marked weakness and occasional gasping with deaths occurring within the first few minutes up to one or two days. We unfortunately did no autopsies on these acute experiments, but I feel certain that they would have shown the marked tissue protein coagulating effect of this bis-aldehyde. Our data on the oral LD<sub>50</sub> in the guinea pig, incidentally, is not far off from that of Henry Smyth's.



Mr. James Morgan--2

October 5, 1965

In the case of skin experiments, these were done as indicated in Patty on the guinea pig using the 30 per cent stabilized solution. It was applied directly to a gauze pad and covered with rubber dental dam as in our usual procedures. Dosages were 5, 10, and 20 ml/kg; all animals were severely affected from systemic toxicity or shock but only the 10 and 20 ml/kg animals died. We noted the yellow staining of the skin mentioned by Carbide, but in addition we had gross, severe, full-thickness necrosis of the entire area under the pad. It is probable that the symptoms were largely the result of the shock from the intense skin necrosis. We did not carry out any eye tests although I feel reasonably certain that severe injury would also have occurred at this concentration.

The only explanation I have for the lack of any effects in Carbide's laboratory is that they may have been using a much more dilute solution or possibly it was incompletely stabilized. Certainly it would be most unlikely for a highly reactive bis-aldehyde, cross-linking agent of this type to be devoid of local irritant effects. As you know, the others in the series such as succinaldehyde and glutaraldehyde are also severe skin irritants. We do not have any data on animal effects by inhalation but from practical experience of chemists the vapors are somewhat irritating to the nose and throat. Usually, however, it is being handled in water solutions and this probably limits the vaporization because of its high degree of water solubility. The vapor pressure is fairly high (estimated to be about 220 mm of mercury at 20° C) so if you had the right conditions you might have inhalation as well as skin problems. Conceivably it could polymerize rapidly in air in which case this might decrease the irritation.

If by any chance you do carry out any experiments of your own, we would be interested to know how your data compares with ours.

Best regards,

*Dave -*

DWFassett, MD: PFN  
cc: Dr. J. A. Zapp

Director  
Laboratory of Industrial Medicine

# Toxicology Studies

GLYOXAL 40%

Attachment E

This is a summary of single exposure studies on animals. The data indicate the relative degree of hazard in handling the product. Increasing degrees of hazard are expressed by these terms: slight, moderate, definite, serious. It must be remembered that results of experiments on animals cannot be numerically translated to probable human response.

The National Research Council defines toxicity as the capacity of a substance to produce injury. Hazard is the probability that injury will result from the handling or use of the substance in the quantity, frequency and manner proposed.

Toxicity is only one factor important in determining the degree of hazard in handling a chemical or in a proposed use. Physical properties of the chemical together with extent and frequency of exposure are equally important.

The term LD<sub>50</sub> has been adopted as a uniform expression of single dose toxicity for comparing one chemical with another. It refers to that quantity of chemical which kills 50 per cent of exposed animals. For further uniformity, quantities are expressed in grams or milliliters of chemical per kilogram of animal body weight.

Single skin penetration refers to a covered 24-hour skin contact with the liquid chemical.

Single Inhalation refers to continuously breathing a certain concentration of chemical vapors for a specified period of time.

Primary irritation refers to the skin response following uncovered skin contact. A covered contact can be expected to have a more severe effect.

Eye injury refers to surface damage produced by contact of the eye with the chemical.

Legal responsibility is assumed only for the fact that all studies reported here, and all opinions, are those of qualified experts.

Single Peroral Dose In Rats: Moderate hazard.

LD<sub>50</sub> - 7.07 milliliters (of product as sold) per kilogram body weight.

For comparison, this product is in the general toxicity range of isopropanol which has an LD<sub>50</sub> value of 5.84 grams per kilogram.

Single Skin Penetration in Rabbits: Slight hazard.

LD<sub>50</sub> - 10 milliliters per kilogram body weight.

This result suggests that skin penetration in harmful amounts is not apt to occur.

Single Inhalation By Rats: Slight hazard.

Breathing the vapors in a state approaching saturation in room air was not fatal to animals in an eight hour exposure.

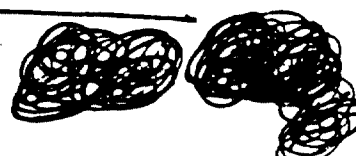
Skin Irritation: Slight hazard.

The undiluted chemical caused redness of short duration on the tender skin of the rabbit belly.

There is reason to believe that repeated skin contact might cause a sensitivity reaction in occasional persons.

For Further Information Write To:  
Industrial Medicine and Toxicology Department  
UNION CARBIDE CORPORATION

270 Park Avenue, New York, N.Y. 10017



GLYOXAL 40%

Eye injury: Slight Hazard.

Flooding the rabbit eye with an excess of the chemical caused a reaction no more severe than moderate inflammation.

GYOXAL 40%

11/12/65

## Triage of 8(e) Submissions

Date sent to triage: \_\_\_\_\_

NON-CAP

CAP

Submission number: 12210A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

Notes:

**THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY**

### For Contractor Use Only

entire document: 0 1 2 pages 1,9 pages \_\_\_\_\_

Notes:

Contractor reviewer: JW Date: 1/17/96

## CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: 1092-12210 SEQ. A

INFORMATION REQUESTED: FLWP DATE: 0501 NO INFO REQUESTED

Submission # 8HQ

0502 INFO REQUESTED (TECH)

TYPE: INT/SUPP FLWP

0503 INFO REQUESTED (VOL ACTIONS)

SUBMITTER NAME: E. I. Dupont de Nemours and Company

0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:

(0505) REFER TO CHEMICAL SCREENING

(0506) CAP NOTICE

SUB. DATE: 10/15/92 OTS DATE: 10/27/92 CSRAD DATE: 02/15/95

CHEMICAL NAME: GYAXAL CASE# 107-22-2

| INFORMATION TYPE: |                          | P F C |    | INFORMATION TYPE: |                           | P F C |    |
|-------------------|--------------------------|-------|----|-------------------|---------------------------|-------|----|
| 0201              | ONCO (HUMAN)             | 01    | 02 | 04                | EPICLIN                   | 01    | 02 |
| 0202              | ONCO (ANIMAL)            | 01    | 02 | 04                | HUMAN EXPOS (PROD CONTAM) | 01    | 02 |
| 0203              | CELL TRANS (IN VITRO)    | 01    | 02 | 04                | HUMAN EXPOS (ACCIDENTAL)  | 01    | 02 |
| 0204              | MUTA (IN VITRO)          | 01    | 02 | 04                | HUMAN EXPOS (MONITORING)  | 01    | 02 |
| 0205              | MUTA (IN VIVO)           | 01    | 02 | 04                | ECOAQUA TOX               | 01    | 02 |
| 0206              | REPRO/TERATO (HUMAN)     | 01    | 02 | 04                | ENV. OCCUREL/FATE         | 01    | 02 |
| 0207              | REPRO/TERATO (ANIMAL)    | 01    | 02 | 04                | EMER INCI OF ENV CONTAM   | 01    | 02 |
| 0208              | NEURO (HUMAN)            | 01    | 02 | 04                | RESPONSE REQEST DELAY     | 01    | 02 |
| 0209              | NEURO (ANIMAL)           | 01    | 02 | 04                | PROD/COMP/CHEM ID         | 01    | 02 |
| 0210              | ACUTE TOX. (HUMAN)       | 01    | 02 | 04                | REPORTING RATIONALE       | 01    | 02 |
| 0211              | CHR. TOX. (HUMAN)        | 01    | 02 | 04                | CONFIDENTIAL              | 01    | 02 |
| 0212              | ACUTE TOX. (ANIMAL)      | 01    | 02 | 04                | ALLERG (HUMAN)            | 01    | 02 |
| 0213              | SUB ACUTE TOX (ANIMAL)   | 01    | 02 | 04                | ALLERG (ANIMAL)           | 01    | 02 |
| 0214              | SUB CHRONIC TOX (ANIMAL) | 01    | 02 | 04                | METAB/PHARMACO (ANIMAL)   | 01    | 02 |
| 0215              | CHRONIC TOX (ANIMAL)     | 01    | 02 | 04                | METAB/PHARMACO (HUMAN)    | 01    | 02 |

## VOLUNTARY ACTIONS:

- (0401) NO ACTION REPORTED  
0402 STUDIES PLANNED/IN PROGRESS  
0403 NOTIFICATION OF WORKER RIGHTS  
0404 LABEL/MSDS CHANGES  
0405 PROCESS/HANDLING CHANGES  
0406 APP/USE DISCONTINUED  
0407 PRODUCTION DISCONTINUED  
0408 CONFIDENTIAL

## TRIAGE DATA:

## NON-CBI INVENTORY

## SPECIES

## TOXICOLOGICAL CONCERN:

## USE:

## PRODUCTION:

YES

NO

IN PROGRESS

REFR

MUS

RAT

GP

RBT

LOW

MED

HIGH

YES (DROP/REFER)

NO (CONTINUE)

CAS 5R

107-22-2

12210A

M

Glyoxal 30%: Acute oral toxicity in mice and rats is of moderate concern. The oral LD<sub>50</sub> values are 400-800 mg/kg in mice and 200-400 mg/kg in rats. Clinical signs included marked weakness and occasional gasping. [The intraperitoneal LD<sub>50</sub> values were 200-400 mg/kg in mice and <100 mg/kg in rats.]

L

Glyoxal 30%: Acute oral toxicity in guinea pigs is of low concern. The oral LD<sub>50</sub> was 800-1,600 mg/kg. Clinical signs included marked weakness and occasional gasping. [The intraperitoneal LD<sub>50</sub> was 100-200 mg/kg.]

L/H

Glyoxal 30%: Acute dermal toxicity is of low concern and dermal irritation is of high concern in guinea pigs. Single dermal doses to guinea pigs at levels of 5,000, 10,000, and 20,000 mg/kg (converted from mL/kg assuming density is 1) were lethal at ≥10,000 mg/kg. Severe, full-thickness necrosis occurred over the entire treatment area.

L

Glyoxal 40%: Acute oral toxicity in rats is of low concern. The LD<sub>50</sub> was 7,070 mg/kg (converted from mL/kg assuming density is 1).

L

Glyoxal 40%: Acute dermal toxicity in rabbits is of low concern. The LD<sub>50</sub> was 10,000 mg/kg (converted from mL/kg assuming density is 1).

L

Glyoxal 40%: Acute inhalation toxicity in rats is of low concern. A single 8-hour inhalation exposure to saturated vapors was not lethal.

L

Glyoxal 40%: Dermal irritation in rabbits is of low concern. Application of the substance to the belly of rabbits resulted in "redness of short duration."

4 M

Glyoxal 40%: Eye irritation in rabbits is of moderate concern. Instillation of the substance into rabbit eyes resulted in moderate inflammation.